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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/320,299	05/26/1999	JEANNETTE WHITCOMB	56534-B/JPW	4512

7590 12/26/2002

COOPER & DUNHAM LLP  
1185 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

[REDACTED] EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
1648	11

DATE MAILED: 12/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/320,299	WHITCOMB, JEANNETTE	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 May, 1999, and 06 March, 2001.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 1-9,17,20,23-31 and 73-79 is/are pending in the application.
- 4a) Of the above claim(s) 1-9,17,20 and 74-79 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 23-31 and 73 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Disposition of Claims

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

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|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

**Detailed Office Action**

***Status of the Claims***

1. Acknowledgement is hereby made of receipt and entry of the preliminary amendment filed 26 May, 1999, wherein claims 10-16, 18, 19, 21, 22, and 32-72 were canceled without prejudice or disclaimer leaving claims 1-9, 17, 20, and 23-31 pending in the instant application. New claims 32-38 [sic-73-79] were submitted in another amendment dated 06 March, 2001. Applicant is advised that the numbering of claims is not in accordance with 37 C.F.R. § 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 C.F.R. § 1.121(b), they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). **Misnumbered claims 32-38 have been renumbered 73-79, respectively.** Applicant must refer to the correct claim numbers in all future communications.

2. Applicant's election with traverse of Group I, including the species directed toward mutations at codon 230, in paper no. 8 is acknowledged. Applicant traverses and argues that the restriction requirement is improper because the inventions of Groups I and II are linked and would not constitute an undue burden on the Examiner if reviewed simultaneously. These arguments are not found persuasive for the reasons of record previously set forth in paper no. 7. The basis for the restriction requirement was clearly laid out in this communication. As previously set forth, the inventions of Groups I and II clearly have different classifications, contrary to applicant's assertion. Moreover, inventions I and II are unrelated. Inventions are unrelated if it can be shown that they

are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case the methodology of Group I  
5 neither requires nor uses the product of Group II. Moreover, the product of Group II can be employed in a variety of different methodologies (i.e., recombinant protein production). Therefore,  
10 each invention is clearly drawn toward a different inventive entity and the restriction requirement was proper. Accordingly, **the original restriction requirement is still deemed to be proper and is therefore made FINAL.**

3. Newly submitted claims 74-79 are directed to an invention that is independent or distinct from the invention originally claimed  
15 for the following reasons: Applicant has introduce new claims 74-79 which are directed toward a drug-screening methodology. The originally presented and elected claims are directed toward prognostic protocols involving HIV-1-infected patients. These inventions are unrelated because they are directed toward different  
20 scientific objectives (clinical outcome v. drug screening) and employ different scientific reagents and methodologies. Thus, contrary to applicant's arguments, these inventions are independent and distinct and would require separate searches. Accordingly, claims 74-79 are withdrawn from further consideration as being  
25 directed towards a nonelected invention (refer to 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03).

4. Claims 1-9, 17, 20, and 74-79 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as  
30 being drawn to a non-elected invention. Claims 23-31 and 73 are currently under examination.

**Drawings**

5. The drawings filed in this application are objected to by the Draftsperson under 37 C.F.R. §§ 1.84 or 1.152 as indicated. These drawings are acceptable for examination purposes only. Formal drawings with the appropriate corrections will be required when the application is allowed. Applicants are reminded to amend the specification (i.e., brief description of the figures including panel descriptions) if necessary when submitting corrected drawings.

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**Information Disclosure Statement**

6. The information disclosure statement filed 27 December, 1999, has been placed in the application file and the information referred to therein has been considered.

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**35 U.S.C. § 112, Second Paragraph**

7. Claims 23-31 and 73-79 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The reference to "HIV-infected" patient and "HIV reverse transcriptase" is vague and ambiguous. Perusal of the disclosure indicates that applicant detected mutational changes in the *pol* gene of HIV-1. However, the reference to HIV in the claim language is confusing since it is not readily manifest if applicant is detecting mutational changes in the HIV-1 or -2 RT that are associated with NNRTI resistance. Appropriate correction is required (i.e., A method of assessing ... in an HIV-1-infected patient ... encoding an HIV-1 reverse transcriptase (RT) ...).

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**35 U.S.C. § 103(a)**

8. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office

action:

5                     (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10                  Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

15                  9. An initial search of the prior art was conducted with respect to mutational changes at amino acid position 230 of the HIV-1 RT. The prior art failed to teach or suggest that this mutation was associated with NNRTI resistance. Accordingly, a search of the prior art was extended to mutational changes in codon 181 (claims 28-31 and 73). Prior art was identified with respect to this mutation and the following rejection is set forth.

20                  25                  10. Claims 28-31 and 73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Larder (1992). Larder teaches that mutations in the HIV-1 RT at positions 106 and 181 are associated with decreased susceptibility to NNRTI therapy. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to collect plasma samples from HIV-1-infected patients and evaluate them for the presence of mutational changes and positions 181 and 106 as taught by Larder (1992). The actual methodologies employed are routine and the art and simply a matter of routine experimentation. For example, the skilled artisan could use PCR to amplify patient sequences or clone various viral isolates using routine procedures.

**Correspondence**

11. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

12. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

13 December, 2002